

WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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Office of West Virginia Secretary Of State

NOTICE OF PUBLIC COMMENT PERIOD

AGENCY:

Health Care Authority

TITLE-SERIES:

65-29

RULE TYPE:

Legislative

Amendment to Existing Rule: Yes

Repeal of existing rule:

No

RULE NAME:

Exemption form Certificate of Need

CITE STATUTORY AUTHORITY:

16-2D-4(a)(2); 16-2D-11; 16-29B-8(a)(1)

COMMENTS LIMITED TO:

Written

DATE OF PUBLIC HEARING:

LOCATION OF PUBLIC HEARING:

DATE WRITTEN COMMENT PERIOD ENDS: 09/23/2020 5:00 PM

COMMENTS MAY BE MAILED OR EMAILED TO:

NAME:

April L Robertson

ADDRESS:

One Davis Square

One Davis Square

EMAIL:

april.l.robertson@wv.gov

PLEASE INDICATE IF THIS FILING INCLUDES:

RELEVANT FEDERAL STATUTES OR REGULATIONS:

No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

INCORPORATED BY REFERENCE:

No

(IF YES, PLEASE UPLOAD IN THE SUPPORTING DOCUMENTS FIELD)

PROVIDE A BRIEF SUMMARY OF THE CONTENT OF THE RULE:
This legislative rule establishes the general criteria and procedures for applying for an exemption from Certificate of Need.
SUMMARIZE IN A CLEAR AND CONCISE MANNER CONTENTS OF CHANGES IN THE RULE AND A STATEMENT OF CIRCUMSTANCES REQUIRING THE RULE:
HB 4108 passed during the 2020 Regular Legislative Session and eliminated the \$1,000 certificate of need exemption application filing fee.
SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED RULE:
A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:
DHHR estimates an average net loss of of \$95,000 from the elimination of this fee.
B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:
C. ECONOMIC IMPACT OF THE RULE ON THE STATE OR ITS RESIDENTS:

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2020 Increase/Decrease (use "-")	2021 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost			
Personal Services			
Current Expenses			
Repairs and Alterations			
Assets			
Other			
2. Estimated Total Revenues	112,000.00	78,000.00	-95,000.00

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

The amount of revenue received from CON exemption applications filing fee was \$112,000 in 2018 and \$78,000 in 2019 resulting in an average net loss of \$95,000.

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

April L Robertson -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

65CSR29

TITLE 65 LEGISLATIVE RULE HEALTH CARE AUTHORITY

SERIES 29 EXEMPTION FROM CERTIFICATE OF NEED

§65-29-1. General.

- 1.1. Scope. -- This legislative rule establishes the general criteria and procedures for applying for an exemption from Certificate of Need.
 - 1.2. Authority. -- W. Va. Code §16-2D-4(a)(2), §16-2D-11 and §16-29B-8(a)(1).
 - 1.3. Filing Date. -- June 1, 2017
 - 1.4. Effective Date. -- June 1. 2017
- 1.5 Sunset Date. -- This rule shall terminate and have no further force or effect on June 1, 2022. upon the expiration of five years from its effective date.

§65-29-2. Definitions.

As used in this legislative rule, all terms that are defined in section 2 of the statute W. Va. Code §16-2D-2 have those same meanings which are in some cases further clarified in this rule. All terms not defined in the statute W. Va. Code §16-2D-2 have the following meanings unless the context expressly requires otherwise.

- 2.1.a. "Authority" means the West Virginia Health Care Authority which is designated to administer the Certificate of Need program by W. Va. Code §16-29B-1116-2D-3(a)(1).
- 2.1.b. "Medically underserved population" is defined on a county-by-county basis. Applicants seeking an exemption for a proposed new end-stage renal disease treatment facility under this rule shall identify the service area as the county where the new facility is proposed to be located. For purposes of this rule only, a county service area with fewer than 50,000 residents is deemed to be a medically underserved population if there is no kidney disease treatment center located less than six driving miles from the location provided in the exemption application.
- 2.1.c. "Statute" means the West Virginia Health Care Authority Certificate of Need statute, W. Va. Code §16-2D-1 et seq.
- 2.1.d. "Verification" means a statement made under oath before a notary public that the information is knowingly provided and is true and correct.

§65-29-3. General Requirements.

3.1. A health service exempt from certificate of need review by W.Va. Code § 16-2D-11 may not be acquired, offered or developed within this state unless the Authority has issued an exemption for the health service an exemption application has been submitted to the Authority and the Authority has acknowledged in writing that the proposed health service is exempt from certificate of need review.

3.2. A person or health care facility may not knowingly charge or bill for a health service exempted from certificate of need review by W. Va. Code §16-2D-11 without first obtaining an exemption from the Authority submitting an exemption application to the Authority and receiving an acknowledgement in writing from the Authority that the proposed health service is exempt from certificate of need review.

§65-29-4. Application.

An application for an exemption shall, at a minimum, include the following:

- 4.1.a. Name, address, and contact information for the applicant;
- 4.1.b. Name, address, and contact information for the person making the application;
- 4.1.c. Verifications from the person making the application and the CEO of the applicant entity;
- 4.1.d. A copy of the governing body's written authorization empowering the CEO or his or her designee to authorize specified individuals to sign the application and to act on its behalf; and
 - 4.1.e. A detailed description of the project, including but not limited to:
 - 4.1.e.1. The location of the proposal;
 - 4.1.e.2. A detailed statement of the services to be provided;
 - 4.1.e.3. The exemption for which the applicant is applying with the appropriate Code citation;
 - 4.1.e.4. A statement of the circumstances justifying approval of the exemption; and
- 4.1.e.5. A timetable for implementation of the project. In the case of a kidney disease treatment center, the facility must be operational within one year of the approval or the exemption will expire after one year.
- 4.1.f. In the case of an exemption of a kidney disease treatment center, the application shall also contain:
- 4.1.f.1. The address of the proposed facility and a copy of the executed lease or option to lease or option to purchase agreement for the facility; and
- 4.1.f.2. Evidence that there is adequate water and other utilities at the site to support the facility.

§65-29-5. Fee.

The application must be accompanied by a nonrefundable fee of \$1,000. Failure to file the required fee with the application is grounds for denial of the exemption.

§65-29-<u>65</u>. Review Process.

6.1.5.1. Upon receipt of the exemption application and fee, the Authority shall review the application

to determine if the application contains all of the information required by Section 4 of this rule. Failure to provide the required information is grounds for denial of the exemption application.

- 6.2.5.2. Once the application is processed, the Authority will provide notice to the public of its receipt of the application on its website acknowledge in writing that the proposed health service is exempt from certificate of need review.
- 5.3. The Authority will provide notice to the public on its website of its receipt of the application and the acknowledgement of the exemption from certificate of need review.
 - 6.3. An affected party may not file an objection to the exemption request.
 - 6.4. The Authority may not conduct an administrative hearing to review the application.
- 6.5. The Authority must either approve or deny the application within forty five days, or sixty days if the time period is extended. The applicant may request or agree with the Authority to a fifteen day extension of this timeframe.
- 6.6. If the Authority does not approve or deny the application within forty five days, or sixty days if the time period is extended, the exemption is deemed approved.
- 6.7.5.4. In addition to the grounds listed in sections 5 and 6.1 section 5.1 of this rule, the Authority may deny the application of if the applicant is not in compliance with any of the financial disclosure requirements contained in WV Code § 16 5F 1 et seq. W. Va. Code §16-29B-24 and 65CSR13; or is in violation of any of the provisions of WV W. Va. Code §16-2D-1 et seq. or §16-29B-1 et seq. or any of the rules promulgated pursuant to these Code sections.

§65-29-76. Expiration of Exemption.

If a kidney disease treatment facility is not operational within one year from the date of the decision on exemption, the exemption will expire unless good cause can be demonstrated.

§65-29-87. Appeals.

- 8.1.7.1. An appeal of the Authority's decision may be filed with the Office of Judges in accordance with W.Va. Code §16-2D-16.
 - 8.2.7.2. In lieu of an appeal, the applicant may refile an application with the Authority.

§65-29-98. Notification of Completion of Project.

The applicant shall notify the Authority in writing upon the completion of the project. The notification shall contain a brief description of the project, the assigned case file number, the date of the completion of the project and the date that the project became or will become operational.